SECTION 5 - 510(k) Summary

JAN 31 2013

Applicant/Sponsor: Catheter Research, Inc.
5610 W. 82nd St.
Indianapolis, IN 46278

Contact Person: Babacar Diouf
317-872-0074 x3512

Date: 10/03/2012

Proprietary Name: The Advance Catheter for HSG and SIS

Classification Name: Cannula, Manipulator/Injector, Uterine;

Product Code: LKF

Classification Regulation: Unclassified, Pre-Amendment 510(k) Submission

Legally Marketed Devices to Which Substantial Equivalence Is Claimed:

HS and SHG Catheters	K032835
FemVue™ Catheter System	K083690

Device Description: The "The Advance Catheter for HSG and SIS (Advance Catheter) consist of a plastic tube, the distal end of which has an inflatable balloon. When the balloon is inflated inside the uterus, the device seals the cervix. A stopcock is provided at the proximal end of the device to allow inflation of the balloon with a syringe. The center lumen is open through the device to the distal end, and the device has a luer connector at the proximal end for injecting fluids.
An introducing sheath is placed over the tube to provide a stiffener and guide. The sheath can be placed into the endocervix to the level of the internal os with no dilatation required; therefore, allowing the catheter to pass easily through the cervix and into the uterine cavity. The Advance catheter like its predicate will be available in 5F and 7F sizes.

Intended Use: Delivery of diagnostic contrast media agents or saline into the female reproductive tract for examination of the uterus and fallopian tubes

The predicate device is intended for the delivery of diagnostic contrast media agents or saline into the female reproductive tract for examination of the uterus and fallopian tubes.

Summary of Technologies: The subject Advance Catheter has the identical technologies as the predicate device. Both devices are assembled in the same work environment using the same manufacturing lines.
The Advance Catheter is identical in materials and function to CRI's presently marketed product with the exception of the sheath.
The Advance catheter also shares substantially equivalent key features with the FemVue™ Catheter System (K083690), including similar principles of operation for device placement and an equivalent transcervical sheath.

Non-clinical/Clinical Testing: Biocompatibility testing per ISO10993 and performance testing (balloon integrity, tensile testing, flow testing, etc.).

Equivalence Summary			
Item	**Predicate**	**Proposed**	**Comments/Discussions**
Catheter Components	HSG Catheter	The Advance Catheter for HSG and SIS	Substantially Equivalent: No significant differences in design, manufacturing, material, sterilization, or packaging.
Sheath	Tube flaired at the distal end	Tube with two steps and smaller OD	Allows for placement inside cervical canal and increase patient comfort.
Indication for Use	Delivery of diagnostic contrast media agents or saline into the female reproductive tract for examination of the uterus and fallopian tubes	Delivery of diagnostic contrast media agents or saline into the female reproductive tract for examination of the uterus and fallopian tubes	Identical
Procedure	Sheath is placed at the face of the cervix.	Sheath is placed inside the cervical canal.	Enhances ease of insertion (see attached letter from Dr. Charles E. Miller)
Biocompatibility testing and performance testing	Flow rate and joints tensile strength meet set requirements. The product is biocompatible per ISO10993	Flow rate and joints tensile strength meet set requirements. The product is biocompatible per ISO10993	See test reports in sections 15 and 18.

In conclusion, since both catheters are similar, we feel that testing performed on the Advance catheter and the information from the predicates devices are sufficient to support the safety and effectiveness of the Advance catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2013

Catheter Research, Inc.
% Mr. Babacar Diouf
Vice President of Regulatory Affairs and Quality Systems
5610 West 82nd Street
INDIANAPOLIS IN 46278

Re: K123258
Trade/Device Name: The Advance Catheter for HSG and SIS
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: January 9, 2013
Received: January 23, 2013

Dear Mr. Diouf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 - Indications for Use Statement

510(k) Number (if known): **K123258**

Device Name: The Advance Catheter for HSG and SIS

Indications for Use:

The intended use of "The Advance Catheter for HSG and SIS" is for the delivery of contrast media or saline during hysterosalpingogram (HSG) and saline infusion sonohysterography (SIS) into the female reproductive tract for examination of the uterus and/or fallopian tubes.

The following are some clinical indications: suspected polyps, fibroids, adhesions, or endometrial thickening, and/or selective evaluation of fallopian tube patency.

The Advance Catheter for HSG and SIS will be available in 5F size for patients with a nulliparous cervix and 7F size for patients with a multiparous cervix.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109) or Over-The-Counter Use _____

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123258